UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,879	03/22/2001	Takuya Watanabe	2553US0P	9847

23115 7590 07/12/2004

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,879	WATANABE ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9,15,17 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,15,17 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed 4/16/04 has been entered. Claims 2-3, 10-14, 16, 18-20 and 22-28 are cancelled. Claims 1, 4, 6, 9, 15 and 17 are amended. Claims 1, 4-9, 15, 17 and 21 are pending.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application 10-279535, filed in Japan on 01/10/1998. Acknowledgment is made of an English translation (submitted 4/16/04) of the application 10-279535, filed in Japan on 01/10/1998.

3. This application still fails to comply with the sequence rules, 37 CFR 1.821-1.825. Applicant has submitted a Substitute Sequence listing but has not stated that no new matter has been added. A statement disclosing no new matter has been added is required.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action (10/21/03)

Claim Rejection, 35 U.S.C. 112

5. Claims 1-9, 15, 17 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 remains indefinite because the method steps do not achieve the goal of determining a ligand for the G protein coupled receptor (GPCR). An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly

define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved (the method does not contain specific assay steps and a statement how and when the goal of the claim is achieved). The method must contain steps disclosing how the ligand for the GPCR is determined. The claim has been amended with the phrase "bringing a test compound in contact with" the G protein coupled receptor protein. The step of bringing a test compound in contact with the G protein coupled receptor protein does not achieve the goal of determining a ligand for the G protein coupled receptor. Merely contacting a compound with the GPCR does not identify the ligand for said receptor. The method requires other steps that show which compounds contacted with the GPCR are ligands and which are not.

6. Claims 1, 4-9, 15, 17 and 21 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reasons of record in the previous Office Action (10/21/03). The rejection under 35 U.S.C. 101 remains the same for the newly amended claims. Applicants argues the rejection of the nucleic acid claims 4 - 9 should be withdrawn because pending claim 4, as now amended, is specifically directed to a nucleic acid of a defined sequence which encodes for a particular G protein coupled receptor protein. This nucleic acid is useful for producing the protein of Claim 1 using recombinant DNA methods. This is supported by a definite and demonstrated example. Applicants assert, the specification discloses the GPCR of SEQ ID NO: 1 is encoded by the polynucleotide of SEQ ID NO: 3. Thus, a specific utility asserted by the applicants, and well

established in the art for such an invention is that the claimed specific nucleic acid does encode for and enable the production of a particular G Protein coupled receptor protein of SEQ ID NO: 1 by using recombinant DNA technology. Substantial and credible utility is further argued to be demonstrated by Example 2 of the specification, which shows the expression of the claimed nucleic acid in a transformed host cell. Applicants' arguments have been fully considered but not found persuasive. As discussed in the Office Action dated 10/21/03 neither the polynucleotide of SEQ ID NO: 3 or its encoded GPCR of SEQ ID NO: 1 are supported by a specific and substantial asserted utility or a well-established utility. Therefore, production of a particular G Protein coupled receptor protein of SEQ ID NO: 1, which lacks utility, using a polynucleotide of SEQ ID NO: 3, which lacks utility, does not overcome the rejections of record.

Applicants further argue the protein of claim 1, and the dependent claims have an asserted credible, specific and substantial utility. Applicants have asserted a specific utility of the protein of Claim I is involved with diseases of dysfunction of the central function (such as for example, mental diseases comprising anxiety) and to physiological disorders (such as for example, with the growth and function of cells and thus the claimed protein is useful for treating or identifying treatments for such conditions. It is also argued that the asserted utility is a credible utility in that the homology with a previously known protein and the expression pattern of the gene encoding for the claimed protein correspond to the development of the neuronal network and thus related to dysfunction of central function. Applicants have also stated they are willing to submit for the Examiner's review; data which illustrate these gene expression patterns;

demonstrate that the claimed protein is involved in accelerated cell proliferation involved with pathologic abnormalities in transgenic rats (such ms cataract, focal desquamation and dysfunction in the kidney); and that the gene is highly expressed in neuronal tissues as would be expected for a protein involved in central dysfunction. Applicants further state, "This is a substantial utility in that the protein is identified and the nucleic acid encoding for such protein is identified such that direct recombinant DNA techniques can be directed to the expression and manipulation of the identified protein in accord with known methodologies". Applicants' arguments have been fully considered but are not found to be persuasive. The specification discloses the GPCR of SEQ ID NO: 1 is encoded by the polynucleotide of SEQ ID NO: 3. The receptor protein is disclosed to have about 30% homology with MAS (page 47, last paragraph), a GPCR. There is no experimental data provided on the functionality of the claimed GPCR. Based solely on the homology data to MAS and the general classification into the superfamily of GPCRs, the specification discloses the claimed receptor is useful for preventing and/or treating diseases associated with dysfunction of the central function for example, mental disease comprising anxiety, schizophrenia, manic-depressive psychosis, dementia, mental retardation and dyskinesis", page 48, first paragraph. There is no disclosure of the specific activity of claimed GPCR or how to assay for said activity. Further no ligands that bind or activate said protein are disclosed. In light of the specification the skilled artisan cannot come to any conclusions as to the function of claimed GPCR. The utility of claimed protein cannot be implicated solely from homology to the proteins known in the art because the art does not provide teaching stating that all proteins

disclosed have the same activity, same effects and the same ligands and are involved in the same disease states (discussed in previous Office Action). On the contrary, Young (US Patent 5,320,941, see previous Office Action) discloses a polypeptide, which has 25.1% query match with SEQ ID NO: and encodes an oncogene. In light of the specification and art the skilled artisan cannot come to any conclusions as to the function of protein of instant invention. There is no disclosure provided within the instant specification on what specific function the protein of SEQ ID NO: 1 possesses, or how to specifically assay for such, ligands that bind, promoters that activate; nor are any cell types/tissues disclosed that specifically express this protein; nor are any disease states disclosed that are directly related to said protein dysfunction. The claimed receptor may have utility in the future, when it has been further characterized (e.g. its dysfunction or function correlated with a specific disease state) and its ligand characterized. The inclusion in the family of G protein coupled receptors (GPCR) does not constitute either a specific and substantial asserted utility or a well established utility for that particular GPCR or protein for reasons of record (see previous Office Action). A utility to orphan receptor cannot be assigned without knowledge of what disease is associated with claimed receptor dysfunction or what drugs/ligands affect a specific claimed receptor function. The superfamily of G-protein-coupled receptors are highly divergent in their effects and include receptors for hormones, neurotransmitters, paracrine substances, inflammatory mediators, certain proteinases, taste and odorant molecules, and even photons and calcium ions. Members of a sub-family of G-protein-coupled receptors are also highly divergent in their effects, as highlighted by Murdoch, Kenakin and Watson

(see previous Office Action). The problems of using homology detection methods to assigning function to related members of a family are disclosed by Bork and Karp (see previous Office Action. Without knowing a biological significance of the claimed GPCR, one of ordinary skill in the art would not know how to use the claimed invention in its currently available form in a credible "real world" manner based on the diversity of biological activities possessed by the GPCR family. Contrast *Brenner*, 148 USPQ at 694 (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics), with *In re Folkers*, 145 USPQ 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties) or *In re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995) (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement).

For reason given above and in the previous Office Action the disclosure and Applicants' arguments are insufficient to teach one of skill in the art how to use the invention.

7. Claims 1, 4-9, 15, 17 and 21 remain rejected under 35 U.S.C. 112, first paragraph for reasons of record in the previous Office Action (10/21/03). The rejection under 35 U.S.C. 112, first paragraph remains the same for the newly amended claims. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above,

one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed protein (SEQ ID NO: 1), polynucleotide (SEQ ID NO: 3), fragments, variants thereof. Further experimentation is necessary to attribute a utility to the claimed polypeptides and fragments thereof.

In addition, claims 1, 4-5, 7-9, 15, 17 and 21 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1, 4-5, 7-9, 15, 17 and 21 are drawn to an isolated GPCR which at least 95% homologous to the amino acid sequence of SEQ ID NO: 1, polynucleotide encoding said GPCR and method of production and use of said protein. There is no disclosure of how to produce functional GPCRs that are at least 95% homologous to the amino acid sequence of SEQ ID NO: 1 or to use non-functional GPCRs. There is no disclosure of how to produce polynucleotide encoding functional GPCRs that are least 95% homologous to the amino acid sequence of SEQ ID NO: 1 or to use polynucleotide encoding non functional GPCRs. Many of the polynucleotide encoding GPCRs that are least 95% homologous to the amino acid sequence of SEQ ID NO: 1 will not even hybridize to the polynucleotide of SEQ ID NO: 3 due to degeneracy of the genetic code. The scope of the claims encompasses billion of variants. The claimed orphan GPCR activity, associated G-protein and activating ligands have not been disclosed. Neither

the claims nor the specification disclose what specific biological activity is associated with the claimed GPCR. There is no disclosure of the specific compounds that are activated in the signal transduction pathway or what ligand is capable of binding to the polypeptide encoded by the claimed polynucleotide, so as to disclose a specific function for the claimed polynucleotide. Therefore nucleic acid encoding unrelated and inactive proteins are encompassed by the claims. The specification does not disclose how to produce active variants or how to use inactive ones. There is no disclosure of how to assay variants since the natural ligand and function of the claimed invention is unknown. The complex nature of GPCRs and the unpredictability of assigning a function to a receptor with no known ligand or function is described in the previous Office Action, see the teachings of Murdoch, Watson, Kenakin, Karp and Bork. Clearly, a single disclosed sequence does not support claims to orphan GPCRs that are at least 95% homologous to the amino acid sequence of SEQ ID NO: 1 to a polynucleotide encoding orphan GPCRs that are least 95% homologous to the amino acid sequence of SEQ ID NO: 1. Due to the large quantity of experimentation necessary to make and identify the polypeptides with the structural and functional features of instant invention, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said polypeptides undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope. Also due to the unpredictability of the effects of mutation on the structure and function of proteins (since mutations of SEQ ID NO: 1 are also encompassed by the claim), and the breadth of the claim which fail to recite meaningful structural and

functional limitations, would require undue experimentation of the skilled artisan to make or use the claimed invention in its full scope.

Claim Rejection 35 USC § 112, 1st paragraph (Written Description)

8. Claims 1, 4-5, 7-9, 15,17 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has not argued the Written Description rejection.

Claims are drawn to an isolated GPCR which is at least 95% homologous to the amino acid sequence of SEQ ID NO: 1, polynucleotide encoding said GPCR and method of production and use of said protein. The common function of the polynucleotide (SEQ ID NO: 3) encoding the polypeptide (SEQ ID NO: 1), which is based upon a common property or critical technical feature of the genus claimed, is not disclosed. The claims, as written, encompass nucleic acid encoding polypeptides, which vary substantially in length and also in amino acid composition. The instant disclosure of a polynucleotide of SEQ ID NO: 3 encoding the polypeptide of SEQ ID NO: 1 does not adequately describe the scope of the use of the claimed genus, which encompasses a substantial variety of subgenera including polynucleotide encoding full-length proteins, comprising fragments of SEQ ID NO: 3 or encoding polypeptides which are substantially identical to the SEQ ID NO: 1, chimeric proteins, fusion proteins and,

variants, which may encode polypeptides completely, unrelated functionally to the polypeptide of SEQ ID NO:1. A description of a genus of polypeptides may be achieved by means of a recitation of a representative number of polypeptides, defined by amino acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. For example, what regions and fragments of the claimed GPCR contain a definitive structural feature required for protein function? The specification proposes to discover other members of the genus by using screening assays and techniques involving probes, primers, and hybridization. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed. No identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the common attributes or

characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific polypeptide and nucleotide sequences and the inability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe, enable and use the genus as broadly claimed. The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. It is acknowledged that the skill of the artisan in the molecular biology art is high. However, in the current instance, **there is no clear evidence of activity possessed by the claimed genus of polypeptides, the critical special technical feature of the polypeptides or how the critical special technical feature encompassed by the genus claimed relates to function.** Because of the lack of guidance in the prior art and current application, one skilled in the art could not predict if the variants containing fragments of claimed GPCR have the same activity as the protein disclosed in SEQ ID NO: 1, since no activity is disclosed, or if they contain the domain(s) of SEQ ID NO: 1, containing the critical special technical feature of the claimed GPCR, since no critical special technical feature is disclosed.

Pertaining to polynucleotides comprising part of the base sequence of the polynucleotide encoding a protein 95% homologous to SEQ ID NO: 1, the specification does not disclose the critical feature which must be contained in said polypeptide which

is required for activity of the encoded protein. The claim encompasses billions and billions of variants, possibly more variants than atoms in the universe. The skilled artisan cannot envision the detailed chemical structure of the encompassed compounds and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid or polypeptide is itself is required. See *Fibers v. Revel*, 25 USPQ d. 1601 at 1606 (CAFC 1993) and *Amen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description

of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Therefore the specification fails to disclose the activity of the claimed genus of polypeptides, the critical special technical feature of the polypeptides or how the critical special technical feature encompassed by the fragments and variants of claimed GPCR relates to function.

The claims encompass proteins/nucleic acids, which are structurally and functionally unrelated to the protein/nucleic acid of SEQ ID NO:1 and 3. Therefore instant specification fails to provide sufficient descriptive information, such as definitive structural/ functional features of the claimed genus of polypeptides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. Although claims recite "G protein coupled receptor", there is no disclosure of the specific activity of claimed GPCR and how it is specifically assayed The specification nor claims disclose the specific activity of the "orphan receptor" of instant invention nor a description of the conserved regions which are critical to the structure and function of the genus claimed.

There is no disclosure of the signal transduction activity transduced by the claimed genus or orphan receptors, the nature of the signal or specific signal transduction

pathway. The claimed nucleic acid encodes an orphan receptor whose activity, associated G-protein and activating ligands have not been disclosed. Neither the specification nor prior art provide a specific assay for the genus claimed. The claimed nucleic acids might be completely unrelated to the GPCR of SEQ ID NO:3 encoding the polypeptide completely unrelated to SEQ ID NO:1 The complexity of assigning a function and membership into a genus of orphan receptor claimed is highlighted in the references of Murdoch, Watson, Bork and Karp, disclosed above. Assigning function by homology is unpredictable by using the complete sequence of an orphan receptor, let alone using a fragment which may not have any domains related to a particular function. Neither the claims nor the specification disclose what specific biological activity is associated with the claimed GPCR or the special technical feature encompassed by specific fragments associated with a specific activity of the claimed genus. The superfamily of seven transmembrane domain G-protein coupled receptors are specialized proteins designed for chemical recognition of ligands and subsequent transduction of information encoded in those ligands to the machinery of the cell, and the G-protein coupled receptors interact with many diverse compounds having diverse effects(See Kenakin, previous Office Action). The important features which would help to define the G-protein mediated signal transduction activity and define the genus claimed have not been disclosed in the specification nor prior art, e.g. ligand recognition domains, domains that allosterically transmit the presence of that ligand to an intracellular domain, specific G-protein interaction domain. Further the activity transduced is not disclosed or how it relates structure to function.

In conclusion, the claims encompass nucleic acids encoding proteins, which are structurally and functionally unrelated to the protein of SEQ ID NO:1. Therefore instant specification fails to provide sufficient descriptive information, such as definitive structural/ functional features of the claimed genus of polypeptides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. Although claims recite "G-protein coupled receptor", there is no disclosure of the specific activity, encompassed by the GPCR and how it is assayed. Neither the specification nor claims disclose the specific activity of the "orphan receptor" of instant invention nor a description of the conserved regions, which are critical to the structure, and function of the genus claimed. Further methods of use of claimed GPCR are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections, 35 U.S.C. 102

9. Claim 21 remains rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US Patent 5,320,941, see previous Office action). Young discloses an isolated polypeptide (SEQ ID NO:2), which has 25.1% query match to SEQ ID NO:1 of instant application (sequence comparison in previous Office Action). Young discloses an isolated polynucleotide (SEQ ID NO:1), which has 9.7% query match to SEQ ID NO:3 of instant application (sequence comparison is attached in previous Office Action). The polypeptide and polynucleotide disclosed by Young can be classified as a G protein

coupled receptor (based on homology data), which comprises an amino acid sequence substantially identical to the amino acid represented by SEQ ID NO:1, and encodes a polynucleotide comprising a polynucleotide comprising part of the base sequence of SEQ ID NO:1, thereby meeting the limitations of claims 21, absent evidence to the contrary.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
July 8, 2004

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600